

Amendment After Final Rejection  
U.S. Patent Application No. 09/488,762

REMARKS

Reconsideration and continued examination of the above-identified application are respectfully requested.

The single amendment to the claims is editorial in nature. Furthermore, no new search is necessitated by this amendment and no new questions of patentability should arise, since the scope of the subject matter of the amended claim has already been examined by the Examiner by way of dependent claims or through consideration of the application. Finally, this amendment places the application in a condition for allowance, or at the very least, in a better condition for appeal. Accordingly, for these reasons, and since no questions of new matter should arise, entry of this amendment is respectfully requested.

As for the specifics of the amendment, claim 1 has been amended to recite that the adhesive layer is releasable. In other words, the adhesive of the present invention is of the pressure-sensitive variety, i.e., the type that adheres to a surface upon the application of pressure, but can be removed later. Support for the stated characteristics of the adhesive is found at page 23, third and fourth full paragraphs from the top of the page, which contains a description of the medical adhesives used, and this passage notes that an acrylic adhesive is considered preferable for reasons of skin irritation. A person skilled in the relevant art would certainly agree that the acrylic adhesives used in medical applications are not permanent adhesives.

Additionally, the examples, such as Tables 7 and 8, and the accompanying text at pages 32 and 33, show the test properties of the claimed invention and further illustrate that the claimed invention is not permanently bonded to the skin, i.e., that the adhesive is releasable in nature, and that the invention is removable once applied to human skin. For instance, in the final paragraph of

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page 32 of the application, there is an express recitation that the patches of the claimed invention were applied to subjects for a period of 24 hours, confirming that the adhesive is indeed releasable.

At page 2 of the Office Action, the Examiner rejects claims 1-10 under 35 U.S.C. § 102(e), as anticipated by, or in the alternative, under 35 U.S.C. § 103(a), as obvious over Kobylivker et al. (U.S. Patent No. 6,002,064). The Examiner indicates that the rejection set forth in the Office Action dated October 4, 2001 (Paper No. 4) is repeated, and further indicates that the remarks of the applicants have been fully considered, but were not found to be persuasive.

At page 3 of the Office Action, the Examiner responds to the previous arguments of the applicants. Although not specifically labeled as such, the Examiner divides his response into two parts, which are interrelated to some extent. His response deals with two topics: (i) structural differences; and (ii) the nature of the bonding.

For the following reasons, this rejection is respectfully traversed.

First, as for the argument that there is a difference in structure between the "tape or sheet" as claimed, and the articles of Kobylivker et al., the Examiner states that the claim language is of such breadth so as to clearly be anticipated by the articles shown in Kobylivker et al.

In response, the applicants believe that the claims as written are not as broad as the Examiner indicates. For instance, the applicants do not believe that a laminate like a surgical gown can be easily characterized as a medical adhesive tape or sheet. More particularly, the uses of Kobylivker et al. are strictly related to medical gowns, caps, aprons, and related apparel, which are quite different from first-aid adhesive tapes. In addition, the benefits achieved and mentioned

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in the present application with respect to stress relaxation ratios, as well as the other benefits mentioned in the examples would not be relevant to the uses specified in Kobylyivker et al.

Second, as for the argument that Kobylyivker et al. is concerned with permanently bonding the film to substrates, and that the claimed invention is concerned with temporarily adhering the medical adhesive tape or sheet to a patient, the Examiner responds at some length. The Examiner states that the applicants are arguing limitations that are not claimed or reflected in the claims. The Examiner states that the claimed composition and the article resulting from the composition are anticipated by the reference. Therefore, the Examiner concludes that attempts to draw a distinction between the permanent coating or adhesive of Kobylyivker et al. and the claimed invention are not persuasive.

In response, the applicants believe that the Examiner is not appreciating some fundamental structural differences between the two articles, as described above and in the previous response, which is repeated and incorporated by reference. In any case, however, the present amendment to claim 1 now specifies that the claimed invention is a removable article, because the adhesive layer is releasable in nature. A removable article such as the claimed invention is completely different from the permanent laminates described in Kobylyivker et al. Kobylyivker et al. simply does not show a releasable adhesive. In fact, the types of applications shown in Kobylyivker et al. would definitely not work if the adhesive was releasable. Therefore, in view of the large differences in structure and potential uses between the claimed invention and the article shown in Kobylyivker et al., which differences are clearly reflected in the claims, it is clear that Kobylyivker et al. does not and cannot anticipate the claimed invention.

Accordingly, in light of all the reasons set forth above, the anticipation rejection should be withdrawn.

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As for the obviousness issue, the Examiner has previously stated that each of the ingredients is shown within the prior art, and that one of ordinary skill would use these ingredients in combination with one another and in the specified amounts to produce the claimed invention. This is simply not true, for the various reasons set forth below. For instance, this analysis assumes that the adhesive used in the claimed invention is an obvious variant of the adhesive used in Kobylykver et al.

While there are various portions of the cited patent where adhesives are mentioned, such as at column 2, lines 46-49, column 8, lines 46-49, or column 9, lines 35-55, these portions all refer to permanently bonding a film layer to some sort of substrate to form an article. Therefore, any use of Kobylykver et al. as a starting point could not lead to the claimed invention. The claimed invention is not designed to be permanently bound two substrates or layers together, because the adhesive used in the claimed invention is not a permanent adhesive.

Adhesives vary greatly; this is why there are literally hundreds, if not thousands, of different adhesives known. The properties that make an adhesive suitable for one application may make it unsuitable for a different application. This is especially true in the present context. An adhesive that permanently bonds a tape or dressing to a person's skin, particularly the sort of sensitive or damaged skin found in surgical wounds, might possibly be disastrous in patient care applications. A permanent adhesive is completely different from the pressure sensitive adhesive layer of the present invention, in which a relevant characteristic of the adhesive concerns its removability from skin.

At pages 23 and 24 of the present application, the general classes of adhesives used in the claimed invention are discussed in detail. These adhesives are for purposes of temporarily adhering the medical adhesive tape or sheet to a person, such as a patient. Accordingly, the adhesives of the claimed invention cannot be irritating to skin, which is why the acrylic adhesives are especially preferred, as set

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forth at page 23, fourth full paragraph. The releasable nature of the adhesive layer is clearly reflected in the claims, and must be considered in evaluating the merit of an obviousness rejection.

No similar considerations of removability or non-irritation are discussed in Kobylykver et al., nor would the permanent laminations discussed in that reference lead a person skilled in the art to substitute an adhesive having different properties. The fact that a permanent adhesive is used is unequivocal evidence that the Kobylykver et al. is confined to applications in which the film is permanently bound to another structure. In such applications, removability is an extremely undesirable characteristic, and the main focus of lamination operations is ensuring that once two layers are bonded together, that they never delaminate. Permanent adhesives of the type useful in lamination operations naturally lead away from any consideration of a removable adhesive or any application based on removable adhesives. For this reason, a person skilled in the art in possession of the Kobylykver et al. reference could not change the nature of the adhesive unless he had an intention to create a totally different invention, i.e., a medical adhesive tape that could be applied directly to human skin and removed later. However, such an article is not found or suggested in Kobylykver et al. and therefore it must only arise through the improper use of hindsight.

Therefore, the physical characteristics of the adhesive layer will vary depending on the type of the adhesive, specifically whether the adhesive is used to releasably attach a film to the skin, or permanently adhere the film to a substrate in order to create a laminate. This is another reason why the teachings of Kobylykver et al. lead away from the claimed invention and could not be used to generate the claimed invention.

Finally, it is clear that the stress relaxation ratios set forth at page 23, first full paragraph of the application, are an important component of the claimed invention, and are not shown or suggested by

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Kobylivker et al. When a medical adhesive tape is attached directly to skin, particularly skin that is sensitive or damaged, it is clear that the flexibility is an extremely desirable quality. Although a medical garment may be in close contact with skin, it does not need to match every contour of the skin or respond to every movement of the body to function well. By contrast, a medical adhesive tape that is adhered directly to the skin preferably matches all the contours of the skin and is able to accommodate movement of the body in order to perform its intended function.

In other words, the ability of the medical adhesive tape to flex or deform is an important characteristic of the claimed invention and is intimately related to both the comfort of the user and the ability of the tape to adhere to the skin in spite of movements of the body. A person in possession of Kobylivker et al. would have no reason to seek the particular stress relaxation ratios of the claimed invention, because they are utterly unrelated to the applications shown in Kobylivker et al., in which flexibility is not an important consideration. Therefore, a person of ordinary skill in the art in possession of the teachings of Kobylivker et al. would not be able to generate the claimed invention using that reference as a starting point.

In summary, the benefits achieved and discussed in the present application with respect to a specialized pressure sensitive adhesive, the unique stress relaxation ratios, as well as the other benefits mentioned in the examples, would not be relevant to the uses specified in Kobylivker et al. Therefore, these particular benefits would not be obvious in view of Kobylivker et al., nor would one skilled in the art be motivated to use a polymeric film of Kobylivker et al. for the particular uses set forth in the present application, namely a first-aid adhesive tape. The particular medical adhesive tape including the adhesive layer would simply not be uses or articles taught or suggested by Kobylivker et al., since

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Kobylivker et al. was not concerned with the particular problems solved by the present application.

Additionally, the releasable nature of the adhesive layer must be considered in evaluating patentability.

Accordingly, in light of all the above, the obviousness rejection should also be withdrawn.

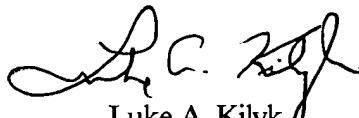
The applicants believe that the foregoing arguments demonstrate the clear patentability of the claimed invention over the cited reference. However, the Examiner is encouraged to contact the undersigned by telephone, if there are any remaining questions concerning the patentability of the present claims or any administrative matters that require attention.

**CONCLUSION**

In view of the foregoing remarks, the applicants respectfully request the reconsideration of this application and the timely allowance of all the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (Amended) A medical adhesive tape or sheet comprising a supporting substrate and [an] a releasable adhesive layer directly or indirectly laminated thereon, wherein said supporting substrate comprises a composition which comprises 100 parts by weight of a thermoplastic resin and 10 to 200 parts by weight of a silicic acid compound.